

DATE

Dear _____,

I am _____'s parent. _____ will be entering _____ at _____ this fall, and _____ has been an incredible resource for _____ and I am so appreciative that we found this community for _____ to continue to learn and grow. However, we now are faced with a very difficult decision.

I am writing to urge _____ to reconsider its decision to mandate the Sars-CoV-2 vaccine as a condition to return to in-person learning without families having to take legal recourse and, rather, to make the vaccine voluntary for at least the upcoming academic year. I also am requesting a zoom (or similar) call to discuss these issues with you and/or the school's counsel after you have had a chance to review this letter and the accompanying materials. Even since _____'s announcing its decision only a few weeks ago, numerous scientific studies from premier universities have been released raising serious questions about the SARS-CoV-2 vaccines.

In consulting with attorneys around the country, I can report that many institutions and employers, when faced with potential litigation over mandating the SARS-CoV-2 vaccines prior to FDA approval, have chosen to suspend or withdraw their mandates, rather than engage in litigation. In fact, many employers are choosing not to mandate even if a vaccine receives FDA approval. For example, a colleague in NJ whose practice focuses primarily on representing employers is advising clients **not** to mandate the vaccines due to potential and uncharted liability.

I have outlined both my legal and scientific/medical concerns below. While I have deep personal religious-based concerns about these interventions, I want to focus on the broader legal and scientific/medical issues that impact all _____ families and staff. I believe that students and staff should have the right, plain and simple, to choose to receive or not receive these injections, without a religious or medical exemption. My goal is not to stop anyone from getting these jabs who wants them but rather to remove the mandate for at least this school year that students and staff must get them.

Proceeding with caution is warranted. There is so much that is unknown about these products, and I am deeply concerned that in 5, 10, or 20 years, we will know much more and perhaps regret this rush to mandate. While we keep hearing that these vaccines are allegedly "safe," we really do not know, it is simply too soon to tell after only a few months (particularly for autoimmunity, which can take years to develop). Much of the science I provide herewith highlights the many unknowns here. Moreover, with hundreds of thousands of injuries and thousands of deaths reported potentially associated with the vaccines, the claim of safety certainly deserves more investigation, as do the injury and death reports. What will _____ do if

one of their students is permanently injured or worse because they were compelled by _____ to receive this injection? Has _____ considered what its damages, financial and otherwise, might be in that situation? There will be continued legal challenges to mandates and likely there will be legal challenges to licensure as well and, in those contexts, it is possible for a court to find that these vaccines are experimental.

I know that you all take the health and well-being of _____ students and staff incredibly seriously, as you have done throughout 2020 and 2021 to date. In the spirit of wanting to do the right thing, I hope you will take the time to read this letter and its attachments and links. The bottom line message is this: a mandate is not legal now because the products are Emergency Use Authorization (and thus by definition experimental and investigational) and should not be mandated even after licensure. I outline these reasons below in more detail:

- Even after licensure, the clinical trials will not be complete for these products for more than a year (and, in the case of Pfizer, approximately 2 years).¹ These products will remain experimental and investigational and the use of these products is a Phase IV post-market trial in which all recipients are part of the trial. <https://www.cdc.gov/vaccines/basics/test-approve.html> As such, adherence to the Nuremberg Code and the U.S. laws and regulations that flow from it is essential.
- These vaccines were rushed to the market and not tested to the standards usually used to assess drugs or biologics (6-10 years);
- We do not have long-term safety data on these vaccines;
- Short-term safety data is not being systematically collected over large populations (and, as noted below, injury data is not being properly assessed);
- Absolute risk reduction for the vaccines is only approximately 1%.² The manufacturers and FDA don't report this but it is in the clinical trial data.;
- Alarming reports of injuries, including deaths potentially related to the vaccine are mounting and are not being properly assessed;
- More and more science is being released, it seems almost daily, calling into question the safety of these vaccines. And more scientists and doctors are speaking out about their concern and experiences. On May 24, 2021, a group of over 50 scientists, doctors, and public policy experts from around the world released a paper identifying risks associated

¹ The Pfizer trials have an estimated completion date of May 2, 2023: (<https://clinicaltrials.gov/ct2/show/NCT04368728?term=NCT04368728&draw=2&rank=1>). and the Moderna trials estimate their completion date as October 27, 2022: (<https://clinicaltrials.gov/ct2/show/NCT04470427?term=NCT04470427&draw=2&rank=1>).

² See Exhibits D(i) and D(ii), also found at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/pdf/medicina-57-00199.pdf> and [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00069-0/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext).

with SARS-CoV-2 vaccines and highlighted the urgent need for independent oversight and monitoring of SARS-CoV-2 vaccine programs, which currently is lacking. (Exhibit A).³

I recognize that this letter is long, but I believe that it contains valuable information for your consideration. I am referring you primarily to peer-reviewed science and interviews and testimony from well-credentialed scientists and doctors at major universities and hospital systems. I hope that you will see that this information raises serious concerns that militate caution.

As discussed further below, vaccine manufacturers have no liability in the event of harm caused by their products, and this lack of liability is in part responsible for public distrust of these vaccines, as it the concern over a rush to market. Not even half those eligible for SARS-CoV-2 vaccines have received them as of this writing, per the CDC's statistics.⁴ The most robust uptake is among the elderly, who often have multiple comorbid health conditions and thus are at higher risk for negative COVID19 outcomes (though even the over-85s have a >98% survival rate). Young people, adolescents, and children are much less likely to have severe COVID19 and thus the risk/benefit analysis is different for these cohorts. Meanwhile, even absent robust vaccine uptake, SARS-CoV-2 cases are extraordinarily low.⁵

³ Also available at: <https://europepmc.org/article/PPR/PPR345192>. After discussing some of the risks observed to date with respect to SARS-CoV-2 vaccines and the many concerning and unanswered questions surrounding SARS-CoV-2 vaccines, the authors state unequivocally:

If vaccination programs worldwide do not institute independent data safety monitoring boards (DSMB), event adjudication committees (EAC), and enact risk mitigation, we will call for a pause in the mass vaccination program. If DSMBs and EACs do not exist currently, as would be imperative for any investigational biomedical program, then vaccination should be immediately halted for those demographic groups at highest risk of vaccine-associated death or serious adverse effects, during the time it takes to assemble these boards and committees and commence their assessments.

In the context of these concerns, we propose opening an urgent pluralistic, critical, and scientifically-based dialogue on SARS-CoV-2 vaccination among scientists, medical doctors, international health agencies, regulatory authorities, governments, and vaccine developers. This is the only way to bridge the current gap between scientific evidence and public health policy regarding the SARS-CoV-2 vaccines. We are convinced that humanity deserves a deeper understanding of the risks than what is currently touted as the official position. An open scientific dialogue is urgent and indispensable to avoid erosion of public confidence in science and public health and to ensure that the WHO and national health authorities protect the interests of humanity during the current pandemic. Returning public health policy to evidence-based medicine, relying on a careful evaluation of the relevant scientific research, is urgent. It is imperative to follow the science.

⁴ <https://covid.cdc.gov/covid-data-tracker/#vaccinations> (as viewed on June 2, 2021, 48.6% of Americans eligible for the vaccines have been fully vaccinated).

⁵ Even Dr. Anthony Fauci had to admit, while testifying before the US Senate on May 11, 2021, that only approximately 60% of employees of his agency are vaccinated, the same is true at FDA, and CDC is not even tracking their rates. While we don't know the reasons for these individuals not having been vaccinated, the vaccine has been widely available for months – especially for those in the healthcare fields.

Doctors and scientists studying these issues at major institutions are increasingly questioning the safety and effectiveness of these vaccines. These well-credentialed professionals are not “anti-vaxxers,” but they have deep concerns about these particular vaccines. Among the many speaking out are Dr. Byram Bridle (Univ. of Guelph in Canada), a viral immunologist who has received substantial government funding to study COVID19 and develop a vaccine, Peter McCullough, MD, MPH, an eminent cardiologist and internist who has taught at Baylor University and now teaches at Texas A&M., and J. Peter Whelan, MD, PhD, a pediatric rheumatologist at UCLA and MassGeneral, who cautioned in December 2020 about many of the vaccine injuries that are being reported today.⁶ Even Dr. Michael Yeadon, a former Pfizer vice-president and chief scientific officer for allergy and respiratory, because of the experimental nature of the technology here, has stated: “we should absolutely not be offering [these vaccines] to young, healthy people who are not at risk from the virus.”⁷

We are just now beginning to learn – and will continue to learn over the next years – the cost of the rush to vaccinate. I would be deeply saddened for _____ students and staff to be forced to be part of what is, essentially, a giant experiment to learn in person and keep their jobs.

I. LEGAL CONCERNS

A. SARS-CoV-2 Vaccines Are Not Approved Products

No SARS-CoV-2 vaccine has yet received full FDA approval. The manufacturers and FDA hurried these vaccines to the public with Emergency Use Authorizations (EUA) to respond to the pandemic. Vaccines usually take 6-10 years for development and clinical trials, not the approximately 1 year for these vaccines. **These vaccines did not proceed in accordance with usual clinical trial and pre-trial protocols**, including extensive animal testing before human trials as well as much longer phase I, II, and III trials to collect efficacy and safety data. Unfortunately, by vaccinating the placebo groups early in the trials (which don’t end for more than 1+ years), the manufacturers essentially wiped out the safety controls in those trials.

While Pfizer applied for a biologics license application from FDA on May 7, 2021, it has not yet been granted and, frankly, given that the clinical trials for these vaccines won't be complete for at least 1+ years, any licensure is likely to be legally challenged. In fact, a citizen's petition recently was filed with FDA to halt all SARS-CoV-2 vaccines and to challenge the granting of the EUAs, particularly where, as here, there are widely available means to treat COVID19 (though, as shown below, these have been suppressed). The petition – which itself contains valuable information and is worth a read – is footnoted for your convenience.⁸ This petition is signed by

⁶ <https://www.regulations.gov/document/FDA-2020-N-1898-0246>

⁷ See

<https://anchor.fm/rfkjr/episodes/Former-Pfizer-Vice-President-Dr--Mike-Yeadon-Speaks-Out-e10fd1h/a-a5qeeak>

⁸ See also <https://www.regulations.gov/document/FDA-2021-P-0460-0001>.

Dr. Meryl Nass, a practicing physician in Maine, who was instrumental in bringing to light troubling legal and medical issues with a prior EUA product – the anthrax vaccine in the military. In that case, the federal district court found that the military could not lawfully mandate an EUA vaccine as soldiers, while risking their lives for the country, could not also be asked to be “guinea pigs.”

B. Mandates Are Not Legal for EUA Products

The SARS-CoV-2 vaccines currently have only Emergency Use Authorization. EUA products are by definition experimental or investigational and thus require the right to refuse. In fact, the CDC itself has said that EUA products cannot be mandated. August 2020 at a meeting of the CDC’s Advisory Committee on Immunization Practices, Dr. Amanda Cohn (the Committee’s executive secretary), stated (beginning @1:14:37): “I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won’t be able to be mandated.”⁹

As noted above, under the Nuremberg Code, no one may be coerced to participate in a medical experiment. Consent of the individual is “absolutely essential.” A federal court held that even the U.S. military could not mandate EUA vaccines to soldiers. *Doe #1 v. Rumsfeld*, 297 F.Supp.2d 119 (2003).

Title 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III) of the Federal Food, Drug, and Cosmetic Act states:

individuals to whom the product is administered are informed—

- (I) that the Secretary has authorized the emergency use of the product;
- (II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
- (III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

Many attorneys and legal scholars have examined the language in the statute in recent months and most agree that, in context, the term “consequences” must be read as potential health consequences of refusing administration as the same sentence also refers to the availability of alternatives and the risks and benefits of those alternatives.¹⁰ Consequences should not be read to include firing, or refusing to allow a student to attend in person learning. This comports with the court’s decision in *Doe #1 v. Rumsfeld* in which the Court found that military members could

⁹ https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/COVID-19Supply-NextSteps_3_LowRes.mp4

¹⁰ <https://www.healthaffairs.org/doi/10.1377/hblog20210212.410237/full/>

not be forced to “serve as guinea pigs for experimental drugs,” in that case, an anthrax vaccine. 297 F.Supp.2d at 135 (military could not punish – including discharge and court martial – those who refused anthrax vaccine). To mandate these vaccines is to violate the fundamental tenets of informed consent.

In March, employees of the Los Angeles Unified School District (LAUSD) sued over the district’s COVID19 vaccine mandate. Only days ago, the California School Boards Association retreated from mandates, though the defendants in the case have not yet admitted defeat in court. A spokesperson for the Association admitted that “K-12 schools or districts, on their own, cannot require the COVID vaccines while the vaccines only have emergency use authorization” and further conceded that “A school or district would likely face public backlash and legal challenges if it decides unilaterally to require COVID vaccinations for students.”

In line with the view of many lawyers and legal scholars,¹¹ New York’s Governor Andrew Cuomo has recognized that these vaccines cannot be mandated absent full FDA licensure, and the University of California and the California State University systems are also withholding a mandate until full licensure because of questions of the legality of a pre-licensure mandate.¹² _____ should also retract its mandate.

C. Even if a Vaccine is Licensed, the Nuremberg Code Requires the Right to Refuse

Even if one of these products is licensed before completion of the Phase III clinical trials, the products remain investigational and experimental, and thus the right to freely refuse the products is protected by the Nuremberg Code and federal law.

The right to fully-informed consent has roots in the Nuremberg Code, which was established following the atrocities of the Holocaust. The first principle of the Code states: “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion.”¹³ Further, specific US laws and regulations similarly protect individuals from being forced to participate in medical experiments, which is precisely what the vaccine roll out amounts to here.¹⁴ Again, these vaccines must be

¹¹ See <https://www.healthaffairs.org/doi/10.1377/hblog20210212.410237/full/> and <https://www.statnews.com/2021/02/23/federal-law-prohibits-employers-and-others-from-requiring-vaccination-with-a-covid-19-vaccine-distributed-under-an-eua/>

¹² See <https://www.thecollegefix.com/governor-cuomo-exempts-faculty-and-staff-from-covid-vaccine-mandate-on-public-campuses/>; <https://hudsonvalleypost.com/cuomo-new-york-state-cant-legally-mandate-vaccine-for-students/>; and <https://www.latimes.com/california/story/2021-04-22/uc-csu-to-require-covid-19-vaccinations-this-fall>

¹³ <https://history.nih.gov/display/history/Nuremberg+Code>

¹⁴ See, e.g., 45 CFR 42 U.S.C. §§ 289, *et seq.*; 45 CFR Part 46 (Basic HHS Policy for Protection of Human Research Subjects, including informed consent at §§ 46.116 and 46.117); 21 CFR Part 50 (Protection of Human Subjects); 21

voluntary. Students should not be forced to receive these shots to learn nor should staff be forced in order to keep their jobs.

The US Court of Appeals for the Second Circuit, which includes Vermont, recognized the principles of the Nuremberg Code in a case involving Pfizer's illegal testing of an antibiotic on Nigerian children:

[S]ignificant world opinion has not come to the defense of the nature or manner in which the experiments were conducted in the Nazi concentration camps." Bassiouni et al., *supra*, at 1641. Rather, since Nuremberg, states throughout the world have shown through international accords and domestic law-making that **they consider the prohibition on nonconsensual medical experimentation identified at Nuremberg as a norm of customary international law.**

Abdullahi v. Pfizer, Inc., 562 F.3d 163, 179 (2d Cir. 2009) (emphasis added and citations and internal quotations omitted).

Moreover, while the health emergency has not been declared resolved, the declining COVID19 case and death rates demonstrate that the emergency in the United States likely has passed and the EUAs should be terminated for that reason as well.

D. Manufacturers Have No Liability

You also may not know that **the vaccine manufacturers are immune from liability (in the absence of fraud or willful misconduct, both of which are difficult to legally demonstrate). No other medical intervention is protected in this way.** See 42 U.S.C. § 300aa-22 and 42 U.S.C. § 247d-6d. In other words, if you or a loved one is injured or dies as a consequence of receiving a vaccine, you cannot sue the manufacturer (this is true for almost all vaccines, not just SARS-CoV-2 vaccines). Instead, you are relegated to federal compensation programs in which the defendant is the US government. These programs are fraught with roadblocks (for example, very short statutes of limitation and no discovery as of right, let alone discovery from non-parties, like the manufacturers). Recoveries are often very limited when they are obtained (usually after many years of contentious litigation). In short, **the vaccine manufacturers are unwilling to stand financially behind their own products and asked the US government to shield them.**

II. MEDICAL/SCIENTIFIC CONCERNS

CFR Part 56 (Institutional Review Boards); 10 CFR Part 745 (Protection of Human Subjects, including informed consent at §§ 745.116 and 745.117).

Within just the last few days and weeks more and more concerning information is coming to light regarding both the effectiveness and the safety of the SARS-CoV-2 vaccines. I will address both below, with citations and articles attached.

A. Vaccine Effectiveness is Questionable

You should also know that the bar for emergency use authorization is quite low – only requiring a showing that a product “may be effective,” and it now appears that these products are not particularly effective. Moreover, vaccinated individuals may still spread COVID to other people, especially if they experience a breakthrough case.

i. Absolute Risk Reduction is Minimal

The manufacturers and the FDA (perhaps in violation of FDA’s own guidelines) have suppressed a critical statistic from the clinical trials: Absolute Risk Reduction (ARR). As one book describes: **“Absolute risk reduction (ARR) – also called risk difference (RD) – is the most useful way of presenting research results to help your decision-making.”**¹⁵ Absolute risk reduction is the difference between the risk of a negative outcome with the intervention versus the risk of a negative outcome without the intervention.

The absolute risk reduction in the SARS-CoV-2 vaccine clinical trials was around 1% (and, for some products, below 1%). However, the manufacturers do not report this information to the public, nor does FDA. I have attached as Exhibit C(i) and C(ii) two articles (including one published in The Lancet) examining the bias in failing to report ARRs and numbers needed to treat. These studies stress the important of reporting ARRs.¹⁶ Americans, in making a decision whether or not to vaccinate, are not receiving critical information about the true effectiveness of these products in order to make a truly informed choice. While relative risk reduction should be reported and suggests that the vaccines may reduce infection in some vaccinated individuals, absolute risk reduction also should be considered. **The fact is that most people are not getting COVID19 regardless of whether they are vaccinated.** Per the CDC, there have been 33,113,930 cases of COVID19 in the US¹⁷ in a population of 332,803,689¹⁸ - in other words, less than 10% of the population, and cases have been dropping precipitously.

ii. Some Breakthrough Cases Are Being Disregarded

Supporting a low absolute risk reduction are the many breakthrough cases, though we may never know how many **because the CDC has stopped tracking breakthrough cases unless an**

¹⁵ See the full discussion at <https://www.ncbi.nlm.nih.gov/books/NBK63647/>.

¹⁶ Also available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/pdf/medicina-57-00199.pdf>: [https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247\(21\)00069-0/fulltext](https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(21)00069-0/fulltext).

¹⁷ https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days

¹⁸ <https://www.worldometers.info/world-population/us-population/> (as of June 2, 2021 at 3:20pm).

individual is hospitalized or dies. ("As of May 1, 2021, CDC transitioned from monitoring all reported vaccine breakthrough cases to focus on identifying and investigating only hospitalized or fatal cases due to any cause."¹⁹ This has raised concerns among many medical and research professionals about the accuracy of COVID19 case reporting going forward and has sparked anger among those patients who have breakthrough cases that will go uncounted.²⁰ However, media are reporting some more well-known breakthrough cases, including eight recent cases among the vaccinated in the NY Yankees organization.²¹

iii. Length of Immunity and Protection from Variants Are Largely Open Questions

Further, no one knows how long vaccine-induced immunity will last and there are now rumblings of frequent boosters, especially for the elderly. Conversely, a new study, attached hereto as Exhibit D, from Washington University School of Medicine suggests that even mild COVID19 cases could induce long-term, perhaps even life-long, immunity.²²

Moreover, as researchers from Harvard, MIT, and elsewhere recently published (Exhibit E):

"The evolvability of SARS-CoV-2 in response to selection pressure will determine the ultimate tractability of our efforts at disease control. Our work suggests that the capacity of SARS-CoV-2 to evade the immune system may be greater than originally anticipated and raises the specter of a process of ongoing and continuous evolution in response to antibody based prophylaxis, occurring on a timescale that may not be convenient or tractable for the design of novel biomedical interventions. **Thus, our findings speak to the need for both public health and biomedical intervention strategies targeting SARS-CoV-2 to be designed to account for the risk of rapid evolutionary response to biomedical interventions.**"

In other words, even absent the effectiveness issues with respect to current prevalent strains, it is expected that the vaccines may have limited impact on some of the new types of the SARS-CoV-2 virus.²³

B. Safety Concerns Continue to Mount

We have known for some time about the potential risk of Antibody Dependent Enhancement (ADE) in the vaccinated should case numbers rise again (and I am aware of at least one case in Italy that recently was determined to be ADE). I can certainly provide more literature on ADE

¹⁹ See <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>.

²⁰ See, e.g., <https://www.nytimes.com/2021/05/25/health/cdc-coronavirus-infections-vaccine.html>.

²¹ <https://www.youtube.com/watch?v=6a0gRUGaa6A>.

²² Also available at https://www.nature.com/articles/s41586-021-03647-4_reference.pdf.

²³ Also available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0250780>.

(whereby a vaccinated individual later exposed to a disease has a worse response than an unvaccinated individual). This phenomenon is one of the reasons SARS and MERS vaccines were unsuccessful. I am hoping that the same is not true here and lessons were learned from attempts to develop those vaccines, but my understanding is that this is a “time will tell” phenomenon, if SARS-CoV-2 is circulating more. I am hearing anecdotal evidence but nothing firm in the scientific literature as of yet and therefore nothing solid to pass on at the moment on ADE.

However, I want to focus on new safety concerns here. In the last several days and weeks, more and more information about potential safety risks of the SARS-CoV-2 vaccines has come to light.

i. Scientists Raise Serious Concerns

Only a few days ago, Dr. Byram Bridle, a viral immunologist at the University of Guelph (Canada), gave an interview to a Canadian journalist, wherein he discussed some of the newest science on COVID19 vaccines. The interview is approximately 9 minutes long but is filled with valuable information and worth the time: <https://omny.fm/shows/on-point-with-alex-pierson/new-peer-reviewed-study-on-covid-19-vaccines-sugge>. Dr. Bridle, whose lab was awarded a \$230,000 grant for COVID19 vaccine development from the Ontario provincial government in 2020, was initially enthusiastic about the prospects of a vaccine.²⁴ However, now studying the science on spike proteins and the vaccines developed, he is very worried. One of the most concerning statements made during his interview is: “We made a big mistake. We didn’t realize it until now ... We thought the spike protein was a great target antigen, we never knew the spike protein itself was a toxin and was a pathogenic protein. So by vaccinating people we are inadvertently inoculating them with a toxin.” Keep in mind that this statement was made by a highly respected viral immunologist who himself was trying to develop a COVID19 vaccine.

I also want to draw your attention to Dr. Peter A. McCullough, M.D., M.P.H. Dr. McCullough is the former Vice Chief of Internal Medicine at Baylor University Medical Center and teaches and practices at Texas A&M Health Sciences Center, and has a host of other credentials. He is one of the most published doctors on COVID19 issues (over 35 peer-reviewed studies). He likely is putting his career on the line to speak out about issues surrounding COVID19 vaccines and COVID19 treatments. He is certainly not anti-vaccine but has grave concerns about the injuries and deaths being reported from the vaccines as well as the lack of support for well-documented treatments that could have potentially saved literally hundreds of thousands of lives had they been made widely available.

- Last week, Dr. McCullough was interviewed by another MD and stated, after having encouraged his high risk patients to get the vaccine initially, “I can no longer recommend

²⁴ See

<https://kitchener.ctvnews.ca/ontario-gives-230k-in-vaccine-research-funding-to-university-of-guelph-1.4948998>.

the vaccine to any individual.”²⁵ He noted that vaccine immunity is nothing like natural immunity and pointed to the 10,000 breakthrough cases that were identified before CDC determined to stop reporting breakthrough cases in the absence of hospitalization or death and indicated that these are estimated to be underreported 10-fold. He also pointed to the risk of vaccination in individuals who previously had COVID19 – these individuals have a higher risk of adverse events following vaccination than those who are COVID-naïve. Like Dr. Bridle, he also noted, providing citations to numerous articles, that the spike protein itself – which is generated in large numbers by the vaccines – is damaging. He also stated that, despite requests that they do so, the CDC and FDA have failed to announce, as is standard practice, the convening of an external clinical events committee and a data safety monitoring committee to provide oversight here.²⁶

- In another interview, Dr. McCullough compared the high number of VAERS reports (discussed below) to the 1976 swine flu vaccination program, which was halted after 500 cases of Guillain-Barré Syndrome and approximately 25 deaths were reported. He also noted that most new drugs would receive a black box warning after about 5 deaths and would be pulled from the market after about 50 deaths. Here there have been over 4,000 potential deaths reported to date.²⁷
- Dr. McCullough also has been an outspoken critic on the US government’s (and other entities) suppression of highly effective early treatments for COVID19. Dr. McCullough and colleagues outlining some of these treatments even before widespread use of Ivermectin, which Dr. McCullough also supports). Dr. McCullough’s and Dr. Harvey Risch have also testified before Congress on early treatment. Dr. Risch is an epidemiology professor at the Yale School of Public Health.²⁸

J. Patrick Whelan, MD, PhD, a pediatric rheumatologist who practices at both UCLA and Massachusetts General Hospital and who teaches at the David Geffen School of Medicine at UCLA submitted a comment to FDA on December 8, 2020 (published the next day) in which he stated, “it appears that the viral spike protein that is the target of the major SARS-CoV-2 vaccines is also one of the key agents causing the damage to distant organs that may include the brain, heart, lung, and kidney.” He was concerned that SARS-CoV-2 vaccines could create a host

²⁵ <https://thehighwire.com/videos/pro-vax-doc-i-can-no-longer-recommend-the-vaccine-to-any-individual/>. Dr. McCullough has been giving multiple interviews in various media outlets willing to share information critical of COVID19 treatments and vaccines.

²⁶ Dr. McCullough discussed government regulators claiming they had reviewed 1,600 deaths from the VAERS system and found no link to any vaccine. Having participated in similar reviews as an external reviewer, Dr. McCullough found this claim incredible (*i.e.*, not credible) because it would take months to amass and review source documents and investigate the circumstances of each death. The regulators speedy review suggests that they did not do this.

²⁷ See also <https://rumble.com/vg6dcd-peter-mccullough-interview.htm>.

²⁸ Their testimony can be viewed here as well: <https://www.hsgac.senate.gov/hearings/early-outpatient-treatment-an-essential-part-of-a-covid-19-solution>.

of ongoing problems that were not addressed in any of the clinical trials. He warned of the need, in particular, to adequately assess cardiac issues. “As important as it is to quickly arrest the spread of the virus by immunizing the population, it would be vastly worse if hundreds of millions of people were to suffer long-lasting or even permanent damage to their brain or heart microvasculature as a result of failing to appreciate in the short-term an unintended effect of full-length spike protein-based vaccines on these other organs.” The link to his letter is footnoted.²⁹

ii. The Vaccine Adverse Events Reporting System (VAERS) Shows Troubling Injuries

The Vaccine Adverse Events Reporting System (VAERS) is the only surveillance system that the US government makes available to the public. VAERS is a passive surveillance system, *i.e.*, reports have to be made to VAERS, VAERS does not actively seek out reports of injury/death following vaccination. VAERS suffers from both under- and over-reporting. Because VAERS alone does not establish causation, inevitably there will be events reported that are not causally related to a vaccination. However, VAERS also has a critical under-reporting problem, with studies showing that, historically, only between 1% and 13% of adverse vaccination reactions are reported to VAERS. *See, e.g.*, Lazarus et al., Electronic Support for Public Health-Vaccine Adverse Event Reporting System, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEPT. OF HEALTH AND HUMAN SERVICES, at 6 (Sept. 30, 2010).³⁰

From December 14, 2020 to May 28, 2021, the CDC makes information public every Friday, 294,801 total adverse events (up 32,300 from 5/21/21) – including 5,165 deaths (up 759 from 5/21/21) – have been reported to VAERS following injection of a SARS-CoV-2 vaccine. That includes 14,691 events in 18 to 25 year-olds (up 1,913 from 5/21/21), including 21 deaths (up 5 from 5/21/21), 710 injuries classified as serious (up 169 from 5/21/21), and 180 classified as life-threatening (up 31 from 5/21/21) in that age cohort. The Medalerts system was used to run this search as it is easier to navigate than the Wonder system. Both systems should yield the same results.

These reports are particularly astounding when four months of reports regarding SARS-CoV2 vaccines are compared to reports concerning other vaccines over decades of VAERS reports (VAERS was established in 1990).

Vaccine	Reports	Serious	Deaths
SARS-CoV-2 (approx. 5 months, through 5/28/21)	329,021 (+34,220)	28,441 (+3,082)	5,888 (+723)

²⁹ <https://www.regulations.gov/document/FDA-2020-N-1898-0246>.

³⁰

<https://digital.ahrq.gov/ahrq-funded-projects/electronic-supportpublic-health-vaccine-adverse-event-reporting-system>.

Influenza (all vaccines; all reports in VAERS without date limitation through to the most recent date available (5/28/21))	189,859 (+13)	19,764 (+8)	1,945 (+0)
Measles (all measles vaccines; all reports in VAERS without date limitation through to the most recent date available (5/28/21))	101,213 (+9)	10,019 (+2)	499 (+0)
HPV (all vaccines; all reports in VAERS without date limitation through to the most recent date available (5/28/21)). ³¹ The first HPV vaccine was licensed in 2006.	67,269 (+9)	9,947 (+7)	586 (+0)

Even accounting for over-reporting (non-related events), but also recognizing substantial under-reporting, the number of deaths and injuries reported to VAERS is a very serious issue that warrants immediate investigation. For any other vaccine, the vaccine would have been pulled from the market long ago (as was done with the swine flu vaccine in the 1970s).

If even a fraction of these reports are causally related to the vaccine, alarm bells should sound. However, CDC has been slow to investigate many of the reported injuries and deaths and has only been public about investigating a few reports related to a few injuries (e.g., blood clots associated with the J&J vaccine and myocarditis in young people). Most reports – including serious injuries and deaths – are apparently languishing, unchecked, while reported events continue to mount.

With respect to myocarditis, dozens of cases have been reported nationwide in teens and young adults, primarily men. In Connecticut alone, there were recently 18 teens/young adults hospitalized with this condition following vaccination.³² Similarly, a healthy young man in Pennsylvania was hospitalized following his second dose of the Pfizer vaccine.³³ While these young people have fortunately appeared to recover (though they likely will need further assessment to determine any lasting effects), a product that potentially induces heart conditions in healthy young people should not be considered safe. In another example of a serious injury following vaccination, a 17 year old in Utah recently developed blood clots in and

³¹ All reports were run without date limitation because at times, for example, a report may not have a vaccination date in the correct field (e.g., the date may be included in the narrative but not at the top of the form or similar issues) and would not be captured otherwise.

³² See <https://www.nbcconnecticut.com/news/coronavirus/connecticut-confirms-at-least-18-cases-of-apparent-heart-problems-in-young-people-after-covid-19-vaccination/2494534/>.

³³ See <https://www.wpxi.com/news/top-stories/local-teen-rushed-hospital-with-trouble-breathing-following-2nd-dose-covid-19-vaccine/MRSTITDZXCKBCIRQCIUKNOBAQ/>

around his brain following inoculation with the Pfizer vaccine.³⁴ A contact in Israel also shared with me that Israeli television reported this week on a possible connection between the second dose of the vaccine (I believe Pfizer is the primary vaccine in Israel) and myocarditis.³⁵

Breaking down the May 21,2021 VAERS data demonstrates reports concerning a wide range of serious injuries and death (recognizing again that VAERS reports are not proof of causation) that are consistent with new science finding that the vaccine-induced spike proteins and/or other vaccine components are traveling to various organs/systems:³⁶

- 20% of deaths were related to cardiac disorders.
- 54% of those who died were male, 44% were female and the remaining death reports did not include gender of the deceased.
- The average age of death was 74.4 and the youngest deaths reported include two 15-year-olds (VAERS I.D. 1187918 and 1242573) and a 16-year-old (VAERS I.D. 1225942). There were other reported deaths in children under 16 that could not be confirmed or contained obvious errors.
- 1,641 pregnant women reported adverse events related to COVID vaccines, including 527 reports of miscarriage or premature birth.
- Of the 2,577 cases of Bell's Palsy reported, 52% were reported after Pfizer-BioNTech vaccinations, 41% following vaccination with the Moderna vaccine and 192 cases, or 9%, of Bell's Palsy cases were reported in conjunction with J&J.
- There were 238 reports of Guillain-Barré Syndrome with 43% of cases attributed to Pfizer, 38% to Moderna and 23% to J&J.
- There were 74,781 reports of anaphylaxis with 39% of cases attributed to Pfizer's vaccine, 50% to Moderna and 10% to J&J.
- There were 4,433 reports of blood clotting disorders. Of those, 1,842 reports were attributed to Pfizer, 1,359 reports to Moderna and 1,194 reports to J&J.

These unprecedented reports of injury and death deserve attention that the CDC does not appear to be giving them.

iii. Recent Studies and Articles

³⁴ See

<https://www.abc4.com/news/local-news/drapper-teenager-hospitalized-with-blood-clots-after-covid-19-vaccine-shot/>.

³⁵ I also have an interim internal report from the Israeli Ministry of Health acknowledging a risk of myocarditis/pericarditis in young people, but the report is in Hebrew. I am happy to forward if you are interested.

³⁶ <https://childrenshealthdefense.org/defender/vaers-data-reports-injuries-12-to-17-year-olds-more-than-triple/> (Children's Health Defense is closely following VAERS reports and the links above take you to the Medalerts reports they ran – you can run those reports or reports in the Wonder system to confirm).

Many of the safety concerns relate to the mRNA vaccines and their lipid nanoparticle (LNP) delivery systems. Certainly the concerns about reactions to polyethylene glycol (PEG) in the Moderna vaccine have been documented and I could provide more information if you need it on that issue. Concerns have also come to the fore concerning the vector-based J&J vaccine (and the Astra Zeneca vaccine not available in the US) concerning blood clots, in particular. But I want to focus on some of the newest science emerging.

We had been told that the spike proteins related to the vaccines express themselves and remain in the cells of the muscles surrounding the injection site before being neutralized. This now appears not to be the case. A lack of knowledge concerning how these spike proteins impact the body leaves many unanswered questions concerning both short and long term negative consequences from these vaccines. Many studies are being published raising questions about the negative effects of the spike proteins and the vaccine delivery systems themselves.

While some of these impacts may be seen in COVID infections as well as the vaccines, a person can take precautions to minimize the risk of infection (which, in any event, is quite low now) versus affirmatively inviting this potential problem through vaccination. Moreover, the risk may be greater from the spike proteins that result from vaccination mechanisms because the lipid nanoparticles used in some of the vaccines transfect cells, and may allow the spike proteins to express on the surface of any cell an LNP can reach (which are most cells), not just cells with ACE2 receptors, as appears to be the case with natural COVID19 infection.

There are many unresolved issues concerning the spike proteins and vaccine delivery mechanisms, including:

- Determining which cells are involved in spike protein production – is it only cells with ACE2 receptors or do the vaccines enable a wider array of cells to produce spike proteins, which could lead to wider inflammatory immune responses and harm (and which might not be immediately apparent)?;
- Determining how controlled or not the production of spike proteins is following injection with mRNA vaccines;
- Understanding how spike proteins enter the blood, how long they stay in the circulatory system, whether they migrate elsewhere from the bloodstream or are neutralized there, and what impact they have on the circulatory system and the blood brain barrier, and hence, the nervous system, as well as impacts on other organs/systems;
- Determining whether the spike proteins and/or LNPs have an impact on male and female reproduction and fertility, pregnancy outcomes, fetal development, and even breastfeeding infants;
- Understanding the potential autoimmune impact of widespread spike protein expression and/or LNPs.

We don't know the answers to these very concerning questions, which should militate in favor of caution. But more information is surfacing, showing that these are among the questions we should be asking before demanding that everyone get vaccinated with experimental products.

For example, a small study from Harvard University and Brigham and Women's Hospital finding spike proteins in blood plasma of vaccinated employees raises questions about the mechanism by which these vaccine-induced spike proteins escape the cells in which they are produced and where (if anywhere) the proteins go when they "clear" the blood.³⁷ The study highlights, however, how limited the understanding of the vaccines' mechanisms of action are:

"We hypothesize that the cellular immune responses triggered by T-cell activation, which would occur days after the vaccination, lead to direct killing of cells presenting spike protein and an additional release of spike into the blood stream. The mechanisms underlying release of free S1 and the subsequent detection of the intact spike protein remain unclear and require further studies." *Id.*

Information concerning spike proteins in the blood following inoculation is particularly troubling when considered in light of research from the Lewis Katz School of Medicine at Temple University shows that SARS-CoV-2 spike proteins promote inflammatory responses on the cells that form the blood-brain barrier and can cause the BBB to become "leaky." This phenomenon potentially results in neurological issues.³⁸ Further study should be done to determine if this is a potential mechanism in spike proteins produced following inoculation.

Another article published on December 31, 2020, recognized the knowledge gap here, and concluded that :

The effects of the SARS-CoV-2 spike protein on the cells of other tissues/organs, such as those of the systemic vasculature, heart, and brain, should also be investigated. Given that this protein will be administered as vaccines to millions and possibly billions of people, **it is critical to understand the extracellular and intracellular effects of the SARS-CoV-2 spike protein on human cells that may promote long-term adverse health consequences.**

(emphasis added).³⁹ Likewise a different study, published in January 2021, concluded that with respect to the vaccines

... we need to consider their long-term consequences carefully, especially when they are administered to otherwise healthy individuals as well as young adults and children. In addition to evaluating data that will become available from

³⁷ Also available at <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab465/6279075>.

³⁸ Also available at <https://www.sciencedirect.com/science/article/pii/S096999612030406X?via%3Dihub>.

³⁹ Also available at <https://www.mdpi.com/2673-527X/1/1/4/htm>.

SARS-CoV-2 infected individuals as well as those who received the spike protein-based vaccines, **further investigations of the effects of the SARS-CoV-2 spike protein in human cells and appropriate animal models are warranted.**

(emphasis added).⁴⁰

Moreover, information that Dr. Bridle and colleagues received as a result of an information request to the Japanese government shows disturbing biodistribution of nanoparticles from the Pfizer vaccine, with accumulations, based on Pfizer's own animal study, in multiple body systems and organs, including especially high results for ovaries, liver, spleen, adrenal glands, and bone marrow. I have linked the English-language translation and the original Japanese-language version of this document.⁴¹

Another just-published article raised the issue of unintended inflammatory activity of the LNPs combined with mRNA, noting that:

A less natural component of the LNPs is the cationic/ ionizable lipid. Some cationic/ionizable lipids can induce inflammation by activating TLR [toll-like receptor] pathways and cell toxicity. The LNPs that were widely used in preclinical vaccine studies and similar in composition to the ones used for the human SARS-CoV-2 vaccines were shown to have adjuvant effect when complexed with mRNA. However, the potentially inflammatory nature of this mRNA-LNPs platform has not been assessed."⁴²

A newly-published (May 26, 2021) article (pre-print, prior to peer review) (~~Exhibit Q~~) has also elucidated a potential mechanism of harm in the vector-based vaccines (like J&J and Astra Zeneca).⁴³ While the authors assume the safety of the mRNA vaccines, they do not address the literature discussed herein concerning potential safety risks with respect to those vaccines as well. The authors state that changes need to be made to the vector-based vaccines: "Based on our findings, we strongly suggest that the re-optimization of "the Spike open reading frames in vector-based vaccines ... to avoid unintended splice reactions and to increase the safety of these pharmaceutical products." *Id.*

⁴⁰ Also available at <https://www.mdpi.com/2076-393X/9/1/36>.

⁴¹ The original Japanese-language document is on the website of the Pharmaceuticals and Medical Devices Agency: https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_l100_1.pdf#page=16.

⁴² Also available at <https://www.sciencedirect.com/science/article/abs/pii/S1879625721000304?via%3Dihub>.

⁴³ Also available at <https://www.researchsquare.com/article/rs-558954/v1>; see also <https://www.wsj.com/articles/scientists-say-they-found-cause-of-blood-clotting-linked-to-astrazeneca-vaccine-11616169108>.

A recently published commentary⁴⁴ by Dr. Hamid A. Merchant, a member of the Department of Pharmacy, School of Applied Sciences, University of Huddersfield, in the United Kingdom, on the European Medicines Agency's warnings concerning SARS-CoV-2 vaccines noted that:

EMA [recognizing a possible link between vaccines and thrombotic events] has also taken additional measures to include information on thrombotic risks in the vaccine's summary of product characteristics (SmPC) and product information leaflets. Furthermore, EMA issued warnings to the patients and healthcare professionals to be vigilant. EMA also published an extended list of symptoms which, if found persistent beyond 3 days of vaccination, patients should seek a prompt medical assistance. The list of symptoms included breathlessness, pain in the chest or stomach, swelling or coldness in an arm or leg, severe or worsening headache or blurred vision, persistent bleeding, multiple small bruises, reddish or purplish spots, or blood blisters under the skin. EMA urged the healthcare professionals to be alert for potential risk of thromboembolism in vaccinated individuals.

Dr. Merchant also noted that the discovery, discussed above, of "an antibody from vaccinated individuals which [scientists] suspect being responsible for attacking platelets and causing recent thrombotic events ... also supports [his] hypothesis that CoViD genetic vaccines may have a direct role in spurring autoimmune response against platelets that may clinically manifest in thrombocytopenia, haemorrhage, and blood clots." *Id.*⁴⁵

In sum, recent (some published only days ago) scientific publications – of which only a few examples have been highlighted – raise serious concerns about these vaccines and should inform any decision of whether or not to mandate the vaccines, either now or if any are given full approval by FDA.

III. CONCLUSION

To reiterate, I am asking _____ to remove its mandate for the Sars-CoV-2 vaccine for students this fall and to simply make vaccination voluntary at least for this academic year. As I am sure you would as well, I would like _____ to be able to focus not on issues related to these investigational products but to continue its critical focus of providing high quality education to students with learning differences.

I thank you for taking the time to go through all of this information. I do realize it is a great deal of data. I hope that you reconsider and retract the SARS-CoV-2 vaccine mandate for Fall 2021. Again, I would like to meet with you to discuss these issues via Zoom or a similar platform.

⁴⁴ Also available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988638/pdf/40545_2021_Article_315.pdf

⁴⁵ See also <https://www.bmj.com/content/372/bmj.n699/rr-6>.

Best,